

REMARKS

Favorable reconsideration of this application is respectfully requested in view of the previous amendments and the following remarks.

Before turning to the claims, a discussion of a catheter package packaging a catheter as disclosed in this application's specification is provided. The catheter to be packaged includes a stainless steel wire reinforcement member embedded in its tube wall. The catheter package holds the distal end of the catheter in its natural state with no external force exerted thereon. As noted in the paragraph bridging pages 2 and 3 of the application, if such a catheter were to be stored by making the catheter round, plastic deformation of the stainless steel wire at its distal end would be introduced, which would render the catheter unusable at the time of procedure. Also, the catheter package holds the proximal side (but not the distal side) of the catheter in a curled state. This reduces the overall length of the package without introducing plastic deformation to the distal side of the catheter.

Turning now to the claims, amended Claim 1 recites a catheter package packaging a catheter comprising a catheter body having a distal portion and a proximal portion, a tube wall defining a lumen passing through from the distal portion to the proximal portion and a metal reinforce member embedded in the tube wall, and a connector part fixed to the proximal portion of the catheter body. The catheter package holds the distal portion of the catheter of 10 to 50 cm in length in a natural state with no external force exerted thereon, and the catheter package holds the remaining proximal side of the catheter in a curled state with a curvature diameter of 10 to 50 cm.

Claim 1 is rejected under 35 U.S.C. § 102(b) as being anticipated by the Hoste patent.

Hoste discloses a catheter with multi-layer wire reinforced wall construction.

In rejecting Claim 1 as being anticipated by Hoste, the Official Action takes the position that Hoste discloses a catheter as recited. The Official Action also takes the position that the claim requires only that the recited catheter be capable of being held by a catheter package in the manner claimed, and that Hoste's catheter is indeed capable of being held in this manner.

However, that is not actually so. Indeed, the language in Claim 1 recites that the distal portion of the catheter of 10 to 50 cm in length is held in a natural state while the remaining proximal side of the catheter is held in a curled state with a curvature diameter of 10 to 50 cm. Thus, the claim language does not recite the capability of the catheter being held, but rather that the catheter is held as claimed.

Nevertheless, the Claim 1 wording is changed to make more clear that which is intended by the original language in Claim 1. The rejection of the claim as being anticipated by Hoste cannot stand in view of the amended claim reciting that the catheter package holds the distal portion of the catheter in a natural state and the proximal side of the catheter in a curled state. Indeed, paragraph 2 of the Official Action includes the statement that "Hoste... does not disclose the states in which the catheter is held in a packaging."

For at least the above reasons, Claim 1 is allowable over Hoste, and withdrawal of the rejection of Claim 1 as being anticipated by Hoste is respectfully requested.

Claim 1 is also rejected under 35 U.S.C. § 103(a) as being unpatentable over the Hoste patent in view of the Bazaral and Van Es patents.

Bazaral and Van Es each disclose distinct catheter packages.

The Bazaral package is a tray-type package that holds substantially the entirety of a catheter, including both ends of the catheter, in a curled state. Applicants respectfully submit that an ordinarily skilled artisan would have recognized that this package is designed for catheters without wire reinforcement. As discussed above, the package would render a catheter having wire reinforcement unusable at the time of the procedure due to plastic deformation of the wires at the distal end.

The Van Es package is a card-type package designed to hold a catheter straight.

The Official Action states that

it would have been obvious to one of ordinary skill in the art at the time the invention was made to enclose the proximal half of Hoste in a plastic compartment/tray as disclosed by Bazaral to keep the distal portion protected from microorganisms and particles while the proximal portion is being attached to the appropriate machines. Van Es discloses the distal half held on a card in its natural state so that the catheter is not damaged as it is withdrawn from the plastic/tray. It would have been obvious to one of ordinary skill in the art to hold the distal end in its natural state on a card so that as the card is withdrawn, the distal end is not damaged.

Applicants respectfully disagree for several reasons.

First, it does not follow that enclosing Hoste's proximal portion in a plastic compartment would serve to keep Hoste's distal portion protected from contamination while Hoste's proximal portion is being attached to the "appropriate machines". Clearly, Hoste's proximal portion would need to be removed from any such plastic compartment prior to being attached to a machine, and so no such protection of Hoste's distal portion would be afforded by the proposed combination.

If anything, such reasoning would have led an ordinarily skilled artisan to consider enclosing Hoste's distal portion in a plastic compartment. However, as discussed in detail above, this would have led to Hoste's distal portion being rendered unusable at the time of the procedure, and so an ordinarily skilled artisan would not have made this modification either. Even assuming some basis exists for the Official Action's reasoning with respect to Bazara's catheter package, the Official Action fails to explain what a curled state has to do with protection from contamination.

Second, Van Es does not disclose holding the distal half of a catheter on a card in its natural state so that the catheter is not damaged as it is withdrawn from a tray. Van Es's package is designed to support the entirety of a catheter on a card--there is no tray.

Even assuming that it would have been obvious to have packaged Hoste's catheter in either Bazara's tray-type package or Van Es's card-type package, there is absolutely nothing to suggest that creation of a tray/card hybrid package as proposed would have been preferable or even feasible to an ordinarily skilled artisan. The Official Action fails to explain how a tray-type package and a card-type package could have been integrated together while retaining their respective functions. It is quite clear that the Official Action relies on impermissible hindsight reasoning in proposing this combination of references. "A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1742 (2007).

Moreover, even assuming that the proposed combination would have been obvious, the Official Action has failed to explain how this combination would have resulted in the distal portion of the catheter of 10 to 50 cm in length held in a natural

state, with the remaining proximal side of the catheter held in a curled state as recited. Also, the Official Action also makes no mention of the curvature diameter of the portion of the catheter held in a curled state, much less explains how the proposed combination would have resulted in a curvature diameter of 10 to 50 cm. Indeed, the Official Action discusses only the length of the catheter. For these reasons, the Official Action has failed to make even a *prima facie* case of obviousness.

For at least the above reasons, Claim 1 is allowable over Hoste in view of Bazarán and Van Es, and withdrawal of the rejection of Claim 1 as being unpatentable over Hoste in view of Bazarán and Van Es is therefore also respectfully requested.

New independent Claim 10 recites a catheter packaged in a catheter package, the catheter package comprising a bottom and upstanding sidewalls, the catheter comprising a catheter body having a distal portion and a proximal portion, a tube wall defining a lumen passing through from the distal portion to the proximal portion and a metal reinforce member embedded in the tube wall, and a connector part fixed to the proximal portion of the catheter body. The catheter package holds the distal portion of the catheter of 10 to 50 cm in length in a natural state with no external force exerted thereon, and the catheter package holds the remaining proximal side of the catheter in a curled state with a curvature diameter of 10 to 50 cm.

New Claim 10 is believed to also be allowable over the Hoste, Bazarán, and Van Es patents at least for reasons similar to those discussed above.

The dependent claims are allowable at least by virtue of their dependence from allowable independent claims. The dependent claims also recite further distinguishing aspects of the catheter and catheter package at issue here. For example, new Claim 11 recites that the catheter package comprises a plurality of separate trays, an upstanding sidewall of one of the plurality of trays being in back-to-back relationship with an upstanding sidewall of another of the plurality of trays, and new Claim 12 recites that a cutout extends through the back-to-back upstanding sidewalls, a portion of the catheter being provided within the cutout.

Early and favorable action with respect to this application is respectfully requested.

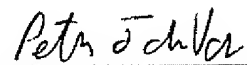
Should any questions arise in connection with this application or should the Examiner believe that a telephone conference with the undersigned would be helpful in resolving any remaining issues pertaining to this application the undersigned respectfully requests that he be contacted at the number indicated below.

Respectfully submitted,

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